

9121 '99 DET -8 P3 3

September 29, 1999

10/5/99

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

(1) Bone contains a variety of minerals, proteins, amino acids, and enzymes.\*

(2) Calcifood is a unique product that contains all of these nutritional components, including marrow that makes bone a living structure.\*

These statements are made for a dietary supplement containing a proprietary blend of defatted wheat (germ), carrot (root), date (fruit), veal bone, rice bran extract, and peanut (bran). Other ingredients include bovine bone, cellulose, honey, dicalcium phosphate, calcium stearate, and arabic gum. And the name of the product is Calcifood®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

ann M. Holden

67492

LET 4375

